



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

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HM32/1023

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/288,344	04/08/99	054	CRANE, L	1623 10/01/01
First Named Applicant	SEIDMAN, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION: METHOD OF TREATING IBD/CROHN'S DISEASE AND RELATED CONDITIONS WHEREIN DRUG METABOLITE LEVELS IN HOST BLOOD CELLS DETERMINE SUBSEQUENT DOSAGE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 P-PM-3474	514-045.000	M96	UTILITY	YES	\$640.00	01/02/02

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

23

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

An Examiner's Amendment to the record appears below. Should the
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or
previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

- ☒ This communication is responsive to amdt. O/ declaration/ IDS, filed 07/05/01
- ☒ The allowed claim(s) is/are 1-10, 13, 16-22, 27-30, 33-38, 44-51 & 55-72 - payment
- ☒ The drawings filed on 12/19/2000 are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) 13, the term "a" (first occurrence) was

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS
FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of
time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or
declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS-18, the term beginning, thereby reducing

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____

☐ including changes required by the proposed drawing correction filed on _____, which has been approved
by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings.
The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right-hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER).
If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF
ALLOWANCE should also be included.

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). --10&21-----

☐ Notice of Draftperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413 (8² paper numbers 19 & 22)

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

09/288,344
PTOL-37 (Rev. 10/95)

COPY FOR (41) File [] Applicant

U.S. GPO: 1997-417-381/62707

Art Unit 1623

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

5 An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

10 In claim 1, at line 7, the term "a" was deleted in favor of the term -- the --.

In claim 1, at lines 9 and 13, the term "a" (first occurrence) was deleted in favor of the term -- the --.

15 In claim 1, at lines 9-10 and 13-14, the term "a level corresponding to" was deleted.

In claim 7, at lines 6, 9, 12 and 13, the term "a" was deleted in favor of the term -- the --.

In claim 7 at lines 16-18, the term beginning " , thereby reducing ..." and the two following lines were deleted.

20 In claim 19 at lines 6, 9, 12, 16 and 21, the term "a" was deleted in favor of the term -- the --.

In claim 19 at line 15, the entire line was deleted.

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In claim 19 at lines 18-20 and lines 24-25, the term
“, thereby reducing the toxicity ... gastrointestinal disorder” was deleted.

In claim 30 at lines 5, 7 and 11, the term “a” was deleted in favor of
the term -- the --.

5 In claim 35 at lines 6, 9, 12 and 16, the term “a” was deleted in
favor of the term -- the --.

In claim 35 at line 15, the “thereby increasing therapeutic efficacy,”
was deleted.

10 In claim 35 at lines 20-22, the term
“, thereby reducing the toxicity ... gastrointestinal disorder” was deleted.

Claims 52-54 were cancelled without prejudice.

In claim 55 at lines 8, 11 and 15, the term “a” was deleted in favor
of the term -- the --.

15 In claim 55 at line 14, the “thereby increasing therapeutic efficacy,”
was deleted.

In claim 55 at lines 17-19, the term
“, thereby reducing the toxicity ... gastrointestinal disorder” was deleted.

In claim 64 at lines 4, 9 and 13, the term “a” was deleted in favor of
the term -- the --.

20 In claim 64 at line 12, the “thereby increasing therapeutic efficacy,”
was deleted.

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In claim 64 at lines 17-19, the term
“, thereby reducing the toxicity ... gastrointestinal disorder” was deleted.

Authorization for this Examiner's Amendment was given in a
telephone interview with Ms. Deborah L. Cadena on September 25, 2001.

5 The title has been altered to read as follows:
Method of Treating IBD/Crohn's Disease and Related Conditions
Wherein Drug Metabolite Levels in Host Blood Cells Determine
Subsequent Dosage -- .

The following is an Examiner's Statement of Reasons for Allowance:

10 Applicant's argument for the instant method of treatment claims
which provide for adjustment of levels of drug administration as a
function of internal concentrations of metabolites is particularly well
supported by the **Belaiche et al.** (PTO-892 ref. W; applicant's "Exhibit
2") in the paragraph bridging pages 72 and 73 wherein the level of
15 azathioprine had to be adjusted in two patients to avoid toxicity and to
maintain efficacy, respectively.

Any comments considered necessary by applicant must be
submitted no later than the payment of the Issue Fee and, to avoid
processing delays, should preferably **accompany** the Issue Fee. Such
20 submissions should be clearly labeled "Comments on Statement of
Reasons for Allowance."

Papers related to this application may be submitted to Group 1600
via facsimile transmission(FAX). The transmission of such papers must
conform with the notice published in the Official Gazette (1096 OG 30,

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November 15, 1989). The telephone number for the FAX machine now operated by Group 1600 is (703) 308-4556.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached on (703)-308-1701.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

15 LECrane:lec
09/30/01



GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600